

Sheet	1	of	4
-------	---	----	---

<i>Application Number</i>	10/612,603
<i>Filing Date</i>	July 1, 2003
<i>First Named Inventor</i>	Chappey et al.
<i>Art Unit</i>	1648
<i>Examiner Name</i>	Humphrey, L.
<i>Attorney Docket Number</i>	57618-386029

[illegible][illegible]Date  
Considered

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 4

**Complete if Known**

Application Number	10/612,603
Filing Date	July 1, 2003
First Named Inventor	Chappey et al.
Art Unit	1648
Examiner Name	Humphrey, L.
Attorney Docket Number	57618-386029

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	5	ABRAVAYA, K. et al., "Detection of point mutations with a modified ligase chain reaction (Gap-LCR)," 1995, Nucl. Acids Res., 23:675-682	
	6	ALLAIN, J.-P. et al., "Long-Term Evaluation of HIV Antigen and Antibodies to p24 and gp41 in Patients with Hemophilia," 1987, N. Engl. J. Med., 317:1114-1121	
	7	ALTSCHUL, S. et al., "Basic Local Alignment Search Tool," 1990, J. Mol. Biol. 215:403-410	
	8	ALTSCHUL, S. et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," 1997, Nucleic Acids Res., 25:3389-3402	
	9	BARANY, F., "Genetic disease detection and DNA amplification using cloned thermostable ligase," 1991, Proc. Natl. Acad. Sci. USA, 88:189-193	
	10	BARRE-SINOSSI, F. et al., "Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)," 1983, Science, 220:868-871	
	11	COLONNO, R. et al., "Identification of 150L as the Signature Atazanavir (ATV)-Resistance Mutation in Treatment-Naïve HIV-1-Infected Patients Receiving ATV-Containing Regimens," The Journal of Infectious Diseases, May 15, 2004; 189:1802-10	
	12	COTTON, R. et al., "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations," 1988, Proc. Natl. Acad. Sci. USA, 85:4397-4401	
	13	Current Protocols in Molecular Biology, Ausubel, F.M. et al. eds., John Wiley & Sons, NY, 2010 Table of Contents and list of yearly supplements	
	14	FAHAM, M. and COX, D., "A Novel In Vivo Method to Detect DNA Sequence Variation," 1995, Genome Res., 5:474-482	
	15	FISCHER, S. and LERMAN, L., "DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: Correspondence with melting theory," 1983, Proc. Natl. Acad. Sci. USA, 80:1579-83	
	16	FREEDMAN, D., PISANI, R., and PURVES, R., 1980, Statistics, W.W. Norton, New York	
	17	GOEDERT, J. et al., "Effect to T4 Count and Cofactors on the Incidence of AIDS in Homosexual Men Infected With Human Immunodeficiency Virus," 1987, JAMA, 257:331-334	
	18	GUPTA, S. et al., "Combinations of Mutations in the Connection Domain of Human Immunodeficiency Virus Type 1 Reverse Transcriptase: Assessing the Impact of Nucleoside and Nonnucleoside Reverse Transcriptase Inhibitor Resistance," May 2010, American Society for Microbiology, Vol. 54, No. 5, p. 1973-1980	
	19	HIRSCH, M. et al., "Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection: 2008 Recommendations of an International AIDS Society-USA Panel," July 15, 2008, Clinical Infectious Diseases, 47:266-85	
	20	KAN, Y. and DOZY, A., "Antenatal Diagnosis of Sickle-Cell Anaemia by D.N.A. Analysis of Amniotic-Fluid Cells," 1987, The Lancet, 2:910-912	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO:**

**Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 4

**Complete if Known**

Application Number	10/612,603
Filing Date	July 1, 2003
First Named Inventor	Chappey et al.
Art Unit	1648
Examiner Name	Humphrey, L.
Attorney Docket Number	57618-386029

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	21	KARLIN, S. and ALTSCHUL, S., "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," 1990, Proc. Natl. Acad. Sci. USA, 87:2264-2268	
	22	KARLIN, S. and ALTSCHUL, S., "Applications and statistics for multiple high-scoring segments in molecular sequences," 1993, Proc. Natl. Acad. Sci. USA, 90:5873-5877	
	23	KELLAM, P. and LARDER, B., "Recombinant Virus Assay: a Rapid, Phenotypic Assay for Assessment of Drug Susceptibility of Human Immunodeficiency Virus Type 1 Isolates," 1994, Antimicrobial Agents and Chemo., 38:23-30	
	24	LANDEGREN, U. et al., "A Ligase-Mediated Gene Detection Technique," 1988, Science, 241:1077-1080	
	25	LUCAS, S. "The pathology of HIV infection," 2002, Lepr. Rev., 73:64-71	
	26	MAXAM, A. and GILBERT, W., "Sequencing End-Labeled DNA with Base-Specific Chemical Cleavages," 1980, Methods in Enzymology, 65:499-560	
	27	MESSING, J. et al., "A system for shotgun DNA sequencing," 1981, Nuc. Acids Res., 9:309-321	
	28	MYERS, R. et al., "Detection of Single Base Substitutions by Ribonuclease Cleavage at Mismatches in RNA:DNA Duplexes," 1985, Science, 230:1242-1246	
	29	NIKIFOROV, T. et al., "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms," 1994, Nucl. Acids Res., 22:4167-4175	
	30	NORRIS, T., "HIV Update," 2002, Radiol. Technol., 73:339-363	
	31	ORITA, M. et al., "Rapid and Sensitive Detection of Point Mutations and DNA Polymorphisms Using the Polymerase Chain Reaction," 1989, Genomics, 5:874-879	
	32	ORITA, M. et al., "Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms," 1989, Proc. Natl. Acad. Sci. USA, 86:2766-2770	
	33	ORUM, H. et al., "Single base pair mutation analysis by PNA directed PCR clamping," 1993, Nucl. Acids Res., 21:5332-5336	
	34	PCR Strategies, 1995, Innis et al. eds., Academic Press, Inc.	
	35	PEARSON, W. and LIPMAN, D., "Improved tools for biological sequence comparison," 1988, Proc. Natl. Acad. Sci. USA, 85:2444-2448	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO:**

**Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 4 of 4

**Complete if Known**

Application Number	10/612,603
Filing Date	July 1, 2003
First Named Inventor	Chappey et al.
Art Unit	1648
Examiner Name	Humphrey, L.
Attorney Docket Number	57618-386029

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	36	PIATAK, M. et al., "High Levels of HIV-1 in Plasma During All Stages of Infection Determined by Competitive PCR," 1983, Science, 259:1749-1754	
	37	POPOVIC, M. et al., "Detection, Isolation, and Continuous Production of cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS," 1984, Science, 224:497-500	
	38	RICHMAN, D., "Resistance, Drug Failure, and Disease Progression," 1994, AIDS Research Hum. Retroviruses 10:901-905	
	39	RUSSELL, W. et al., "Specific-locus test shows ethylnitrosourea to be the most potent mutagen in the mouse," 1979, Proc. Nat. Acad. Sci. USA, 76:5818-5819	
	40	SAMBROOK et al., 2001, Molecular Cloning : A Laboratory Manual, Cold Spring Harbor Laboratory, 3rd ed., NY	
	41	SANGER, F. et al., "DNA sequencing with chain-terminating inhibitors," 1977, Proc. Natl. Acad. Sci USA, 74:5463-5467	
	42	SOUTHERN, E.M., "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis," 1975, J. Mol. Biol., 98:503-517	
	43	SYVANEN, C. et al., "A Primer-Guided Nucleotide Incorporation Assay in the Genotyping of Apolipoprotein E," 1990, Genomics, 8:684-692	
	44	THIEDE, C. et al., "Simple and sensitive detection of mutations in the ras proto-oncogenes using PNA-mediated PCR clamping," 1996, Nucl. Acids Res., 24:983-984	
	45	TORELLI, A. and ROBOTTI, C., "ADVANCED and ADAM: two algorithms for the analysis of global similarity between homologous informational sequences," 1994, Comput. Appl. Biosci., 10:3-5	
	46	URDEA, M., "Synthesis and Characterization of Branched DNA (bDNA) for the Direct and Quantitative Detection of CNV, HBV, HCV, and HIV," 1993, Clin. Chem., 39:725-726	
	47	WAGNER, R. et al., "Mutation detection using immobilized mismatch binding protein (MutS)," 1995, Nucl. Acids Res., 23:3944-3948	
	48	WHITCOMB, J. et al., "Broad Nucleoside Reverse-Transcriptase Inhibitor Cross-Resistance in Human Immunodeficiency Virus Type 1 Clinical Isolates," 2003, J. Infectious Diseases, 188:992-1000	
	49	YOUIL, R. et al., "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII," 1995, Proc. Natl. Acad. Sci USA, 92:87-91	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.